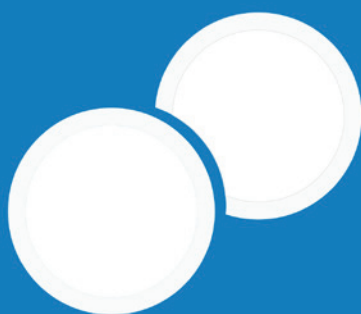
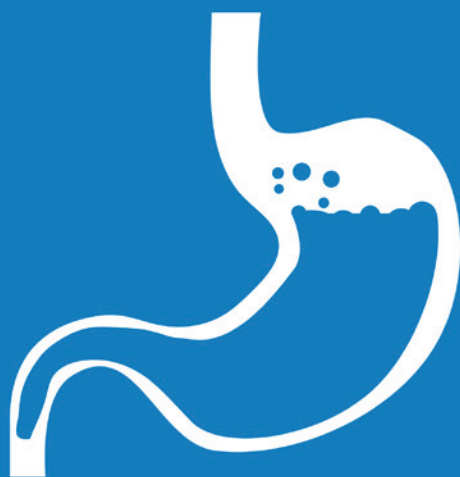


# Warning: Aspirin-Containing Antacid Medicines Can Cause Bleeding



**Upset stomach?  
Consider an antacid  
without aspirin.**



**T**he next time you reach for an over-the-counter (OTC) product to treat your upset stomach or heartburn, consider whether you should use one of the many antacids that don't have aspirin.

Why? Aspirin-containing medicines to treat heartburn, sour stomach, acid indigestion, or upset stomach can cause stomach or intestinal bleeding, especially in some people, warns the U.S. Food and Drug Administration (FDA).

Cases of bleeding are rare. In 2009, FDA issued a warning about serious stomach bleeding risk with aspirin and other non-steroidal anti-inflammatory drugs (NSAIDs). Despite that warning, when FDA reviewed its Adverse Event Reporting System database, it found eight new cases of serious bleeding caused by aspirin-containing antacid products since that 2009 warning. Some of those patients required a blood transfusion.

"Take a close look at the Drug Facts label, and if the product has aspirin, consider choosing something else for your stomach symptoms," says Karen Murry Mahoney, MD, Deputy Director of the Division of Nonprescription Drug Products at FDA. "Unless people read the Drug Facts label when they're looking for stomach symptom relief, they might not even think about the possibility that a stomach medicine could contain aspirin."

Mahoney adds: "Today we're focusing on bleeding risk specifically with antacid-aspirin products used to treat upset stomach or heartburn. We're not telling people to stop taking aspirin altogether."

How will you know what OTC medicine to take to get relief from indigestion? Again, it's important to read the Drug Facts label. It will tell you if the product contains aspirin, and it lists the risk factors for bleeding. If the medicine has aspirin, consider looking for something else. There are plenty of stomach medicines that don't contain aspirin.

## **Who's at Higher Risk of Bleeding**

Because aspirin thins the blood, FDA believes the aspirin in these combination medicines is contributing to major bleeding

*“Today we’re focusing on bleeding risk specifically with antacid-aspirin products used to treat upset stomach or heartburn. We’re not telling people to stop taking aspirin altogether.”*

events. People with one or more risk factors have a higher chance of serious bleeding with aspirin-containing antacid products.

You are at higher risk for bleeding with these products if you:

- Are 60 or older.
- Have a history of stomach ulcers or bleeding problems.
- Take drugs that reduce the ability of your blood to clot (also known as anticoagulants or blood-thinning drugs (<http://www.fda.gov/ForConsumers/ConsumerUpdates/ucm467201.htm>)).
- Take steroid medicine, such as prednisone, to reduce inflammation.
- Take other medicines containing NSAIDs (<http://www.fda.gov/forconsumers/consumerupdates/ucm453610.htm>), such as ibuprofen or naproxen.
- Drink three or more alcoholic drinks every day.

Warning signs of stomach or intestinal bleeding include feeling faint, vomiting blood, passing black or bloody stools, or having abdominal pain. These are signs that you should consult a health care provider right away.

What if you’ve been taking these products for a long time?

“Some people may have been taking aspirin-containing antacid products frequently for a long time. Apart from the bleeding risk, it’s not normal to have frequent or chronic

upset stomach or heartburn. You should talk to a health care provider if that’s happening,” says Mahoney.

Take aspirin regularly? If your health care provider has advised you to take an aspirin a day to help prevent a heart attack (<http://www.fda.gov/ForConsumers/ConsumerUpdates/ucm390539.htm>) or other condition, don’t stop without talking with your doctor first, Mahoney says. Make sure you discuss what kind of medicine you can take in case you get an upset stomach.

### How to Settle an Upset Stomach

Consumers have many alternatives for treating heartburn, sour stomach, acid indigestion, and upset stomach. Read the Drug Facts label and look for products that contain an “antacid” or “acid reducer.”

For example, Mahoney says, there are numerous OTC medicines that contain only an antacid, such as calcium carbonate, magnesium hydroxide, or another antacid. These can be used to treat heartburn, sour stomach, acid indigestion, and upset stomach. For frequent heartburn, there are acid reducers, such as proton pump inhibitors (esomeprazole, lansoprazole, omeprazole), or H2 blockers (cimetidine, famotidine, ranitidine).

### What Else FDA Is Doing

In 2009, a warning (<http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/2009/ucm149573.htm>) about the

risk of serious bleeding was added to the labels of all OTC products that contain NSAIDs, including aspirin-containing antacid products.

FDA is continuing to evaluate this safety issue and plans to convene an advisory committee of external experts in 2017 to provide input regarding whether additional regulatory action is needed, such as adding warnings to the labeling or other actions.

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